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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,494

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Gary P. Cook

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EXAMINER

SHOMER, ISAAC

ART UNIT

PAPER NUMBER

4121

MAIL DATE

DELIVERY MODE

12/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/564,494	COOK, GARY P.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ISAAC SHOMER	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### ***Election/Restrictions – Lack of Unity***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group I, claim(s) 1-16, drawn to a method of making a controlled release composition.
2. Group II, claims 17 and claim 34, drawn to a controlled release composition.
3. Group III, claim(s) 18, 20-33, 35, drawn to a process for the production of microparticles and improvements thereof.
4. Group IV, claim(s) 36-50, drawn to method of making a controlled release composition.
5. Group V, claims 19 and claim 51, drawn to a microparticle composition.

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As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Moreover, as stated in PCT Rule 13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group II is a controlled release composition comprising a bioactive agent, polymer and organic salt. The controlled release composition comprising a bioactive agent, polymer and organic salt of claim 17 does not present a contribution over the prior art. As disclosed in (US 6,706,289, Claims 1-6), [in view of (US. Patent 6,270,700) (Column 11, Lines 30-46 and Column 12 Lines 17-21)] the controlled release composition comprising a bioactive agent, polymer, and organic salt of instant claim 17 does not involve an inventive step. As such, Group II does not share a special technical feature with the instant claims of Groups I and III-V. Therefore,

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the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-V is broken.

### ***Election of Species***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If applicant elects Group I:

1. *Cosolvent* (e.g. dimethyl sulfoxide, dimethyl formamide, n-methylpyrrolidinone) with claim 3 reading upon this species; and
2. *Emulsifying agent* (e.g. poly(vinyl alcohol), albumin, lecithin, polysorbates) with claim 5 reading upon this species; and
3. *Solvent* (e.g. methylene chloride, ethyl acetate, acetone) with claim 7 reading upon this species; and
4. *Controlled release composition* (e.g. microparticles and nanoparticles) with claim 9 reading upon this species; and
5. *Polymer* (e.g. poly(lactide)s, poly(glycolide)s, poly(lactic acid)s) with claim 11 reading upon this species
6. *Bioactive agent* (e.g. proteins, nucleic acids, carbohydrates) with claim 12 reading upon this species; and

7. *Protein or peptide* (e.g oxytocin, insulin, leuprolide) with claim 13 reading upon this species; and
8. *Organic ion* (e.g. carboxylate, sulfate, phosphate) with claim 16 reading upon this species.

If Applicant elects Group III:

1. *Cosolvent* (e.g. dimethyl sulfoxide, dimethyl formamide, n-methylpyrrolidinone) with claim 21 reading upon this species; and
2. *Emulsifying agent* (e.g. poly(vinyl alcohol), albumin, lecithin, polysorbates) with claim 23 reading upon this species; and
3. *Solvent* (e.g. methylene chloride, ethyl acetate, acetone) with claim 25 reading upon this species; and
4. *Controlled release composition* (e.g. microparticles and nanoparticles) with claim 27 reading upon this species; and
5. *Polymer* (e.g. poly(lactide)s, poly(glycolide)s, poly(lactic acid)s) with claim 29 reading upon this species
6. *Bioactive agent* (e.g. proteins, nucleic acids, carbohydrates) with claim 30 reading upon this species; and
7. *Protein or peptide* (e.g oxytocin, insulin, leuprolide) with claim 31 reading upon this species; and
8. *Organic ion* (e.g. carboxylate, sulfate, phosphate) with claim 33 reading upon this species.

If applicant elects group IV:

1. *Cosolvent* (e.g. dimethyl sulfoxide, dimethyl formamide, n-methylpyrrolidinone) with claim 37 reading upon this species; and
2. *Emulsifying agent* (e.g. poly(vinyl alcohol), albumin, lecithin, polysorbates) with claim 40 reading upon this species; and
3. *Solvent* (e.g. methylene chloride, ethyl acetate, acetone) with claim 42 reading upon this species; and
4. *Controlled release composition* (e.g. microparticles and nanoparticles) with claim 44 reading upon this species; and
5. *Polymer* (e.g. poly(lactide)s, poly(glycolide)s, poly(lactic acid)s) with claim 46 reading upon this species
6. *Bioactive agent* (e.g. proteins, nucleic acids, carbohydrates) with claim 47 reading upon this species; and
7. *Protein or peptide* (e.g. oxytocin, insulin, leuprolide) with claim 48 reading upon this species; and
8. *Organic ion* (e.g. carboxylate, sulfate, phosphate) with claim 50 reading upon this species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic:

Claims 1, 2, 4, 6, 8, 10, and 14 as to Group I.

Claims 17 and 34 of Group II.

Claims 18-20, 22, 24, 26, 28, 32 and 35 as to Group III.

Claims 36, 38, 39, 41, 43, and 45 as to Group IV.

Claims 19 and 51 of Group V.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

- a. Each chemical species contains a distinct moiety such that each chemical species is of a dissimilar nature.



There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

### ***Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

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All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on Monday - Thursday 7:30AM - 5:00 PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./

Examiner, Art Unit 4121

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4121